1653

Attorney Docket No.: S0351/186588

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FEB 2 8 200

P#9

In re application of

Patrick J. Burns

Serial No.:

09/336,328

Filed:

For:

June 18, 1999

COMPOSITIONS SUITABLE FOR

CONTROLLED RELEASE OF THE

HORMONE GNRH AND ITS

**ANALOGS** 

Art Unit:

1653

Examiner:

F. Moezie

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Assistant Commissioner for Patents Washington, DC 20231

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Sir:

In accordance with Rules 56, 97 and 98 of the Rules of Practice in Patent Cases (37 C.F.R. §§ 1.56, 1.97, and 1.98), the publications listed on the attached modified Form PTO-1449 are enclosed with this submission for consideration by the Examiner. None of the identified materials is conceded as being prior art within the meaning of the United States patent laws.

This Information Disclosure Statement is being filed before the issuance of a first office action on the merits of the application (37 C.F.R. 1.97(b)(3)); therefore, no fee is

#### **CERTIFICATE OF MAILING (37 CFR 1.8a)**

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U.S.S.N.: 09/336,328 Filed: June 18, 1999

For: Compositions Suitable for Controlled Release of the Hormone GnRH and its Analogs

INFORMATION DISCLOSURE STATEMENT

believed to be due. If a fee is due, the Commissioner is authorized to charge such fee and any additional fees that may be due or credit any overpayment to Deposit Account No. 11-0855.

Respectfully submitted,

Bruce D. Gray

Reg. No. 35,799

Date: February 22, 2001

KILPATRICK STOCKTON LLP Suite 2800, 1100 Peachtree Street Atlanta, Georgia 30309-4530 (404) 815-6218

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Complete if Known				
Application Number	09/336,328			
Filing Date	June 18, 1999			
First Named Inventor	Patrick J. Burns	(0)		
Group Art Unit	1653	0		
Examiner Name	F. Moezie			
Attorney Docket Number	S0351/186588	□ FFR 2		

			U.S. PATENT DOCUM	MENTS	K
Examiner Initials *	Cite No.1	U.S. Patent Document  Number Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2,931,802	Toney	04/05/1960	
		3,853,837	Fujino et al.	12/10/1974	
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		Fore	eign Patent Doc	ument	Name of Patentee or	Date of Publication	Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Office <sup>3</sup>	Number	Kind Code <sup>5</sup> ( <i>if known</i> )	Applicant of Cited  Document	of Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
		DE	1 569 231		Squibb	08/21/1969		
		JP	2096516		Dai Nippon	04/09/1990		<b>√</b>
		JP	7115901		Fuji Beverage	05/09/1995		<b>✓</b>
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		wo	93/07833	A2	Peptide Tech.	04/29/1993		
		wo	98/34596	A2	3M	08/13/1998		

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Sheet	2	of	6

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Application Number	09/336,328	
Filing Date	June 18, 1999	RECE
First Named Inventor	Patrick J. Burns	HEOL
Group Art Unit	1653	MAD
Examiner Name	F. Moezie	MAR 0;
Attorney Docket Number	S0351/186588	TECH CENTER

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U.S. PATENT DOCUMENTS						
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		Fore	eign Patent Doo	cument	Name of Patentee or	Date of Publication	Pages, Columns, Lines,	
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		wo	98/27962	A2	Alza Corp.	07/02/1998		
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		EP	0 537 559	A1	Atrix Labs	04/21/1993		

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Filing Date	June 18, 1999			
First Named Inventor	Patrick J. Burns			
Group Art Unit	1653			
Examiner Name	F. Moezie			
Attorney Docket Number	S0351/186588			

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		6,051,558	Burns et al.	04/18/2000	5
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	FOREIGN PATENT DOCUMENTS							
		Fore	Foreign Patent Document		Name of Patentee or	Date of Publication	Pages, Columns, Lines,	
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INFORMATION DISCLOSURE	Application Number	09/336,328	
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STATEMENT BY APPLICANT	First Named Inventor	Patrick J. Burns	
	Group Art Unit	1653	/O\
(use as many sheets as necessary)	Examiner Name	F. Moezie	/
Sheet 4 of 6	Attorney Docket Number	S0351/186588	

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	,	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	FE
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Examiner	Date	
Signature	Considered	
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NEO	DRAATION	DIC	CL OCUDE	Application Number	09/336,328		
			CLOSURE	Filing Date	June 18, 1999		
SIAT	EMENT B	YA	PPLICANT	First Named Inventor	Patrick J. Burns	-	
				Group Art Unit	1653		
	(use as many she	ets as	necessary)	Examiner Name	F. Moezie	$\overline{}$	
Sheet	5	of	6	Attorney Docket Number	S0351/186588		

Attorney Docket Number

Ю 展 OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS œ Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of Cite T<sup>2</sup> Examiner the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue <u>N</u>o.<sup>1</sup> number(s), publisher, city and/or country where published. Initials \* Ginther, O.J., "Ultrasonic Imaging and Reproductive Events in the Mare," Equiservices, Cross Plains, WI Chapter 4: 43-72 (1986) Harrison, L., et al. "Comparison of HCG, Buserelin and Luprostiol for Induction of Ovulation in Cycling Mares," J. Eq. Vet. Sci., 11:163-166 (1991) Henry, C. "Surcrose Acetate Isobutyrate Special Grade for Beverage Applications" Hyland, J.H., et al. "Infusion of Gonadotrophin-Releasing Hormone (GnRH) Induces of Ovulation and Fertile Oestrus in Mares During Seasonal Anoestrus," <u>J. Reprod. Fert.</u>, Suppl. 35 (1987), 211-220 Irvine, C.H. G., "GnRH Clinical Application," In Equine Reproduction, (eds) McKinon, A.O. and Voss, J.L., Chapter 36, pp. 41-45, Lea & Febiger (1993) Irvine, D.S., et al., "Duration of Oestrus and Time of Ovulation in Mares Treated with Synthetic GnRH (Ay24,031)," J. Reprod. Fert. Supp. 23:279-283 (1975) Jochle, W., et al., "Control of Ovulation in the Mare with Ovuplant™, a Short-Term Release Implant (STI) Containing the GNRH Analogue Deslorelin Acetate: J. Eg. Vet. Sci., 44:632 (1994) Kulkarni et al., "Polyactic Acid for Surgical Implants," Arch. Surg., 93:389 (1966) LaCoste, D., et al., "Reversible Inhibition of Testicular Androgen Secretion by 3-, 5- and 6-Month Controlled-Release Microsphere Formulations of the LH-RH Agonist [D-Trp<sup>6</sup>, des-Gly-NH<sub>2</sub><sup>16</sup>] LH-RH Ethylamide in the Dog," J. Steroid Biochem, 33:5, 1007-1011 (1989) Loy, R.G. et al. "The Effects of Human Chorionic Gonadotrophin on Ovulation, Length of Estrus, and Fertility in the Mare," Cornell Vet. 56:41-50 (1966) Material Safety Data Sheet of Eastman Chemical Products, "SAIB" Sucrose Acetate Isobutyrate," pp. 2-18 Material Safety Data Sheet of Eastman Fine Chemical Pharmaceutical Ingredients, "Sucrose Acetate Isobutyrate Special Grade (SAIB-SG), Publication No. EFC-211, (May 1991) Material Safety Data Sheet of Eastman Products for the Food Industry, "Sucrose Acetate Isbutyrate (SAIB-SG) for Use in Fruit-Flavored Beverages," Publication No. ZM-90, pp. 2-7 (Sept. 1989) Mearns, "Changing Seasons," The Blood-Horse, Sept. 28, 1996, p. 4794-4795

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Signature		Considered	

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Substitute for form 1449A/PTO Complete if Known **Application Number** 09/336,328 INFORMATION DISCLOSURE Filing Date June 18, 1999 STATEMENT BY APPLICANT First Named Inventor Patrick J. Burns

Group Art Unit

**Examiner Name** 

(use as many sheets as necessary)

F. Moezie

Sheet	6	of 6	Attorney Docket Number	S0351/186588	/
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Signature	Considered	

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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.